510(k) Summary
for the APEX Spine System w/ CoCr Rods

DEC 10 2010

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
This special 510(k) is submitted to add Ø5.5mm and Ø6.0mm CoCr Spinal Rods to our existing APEX Spine System.

Date Prepared: 11/16/2010

1. Submitter:
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Contact Person:
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Director of Regulatory Affairs.
SpineCraft, LLC
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2. **Trade name:** APEX Spine System w/ CoCr Rods
Common Name: Pedicle screw system
Classification Name: Pedicle screw spinal system per MNI 888.3070
Pedicle screw spinal system per MNH 888.3070
Spinal interlaminal fixation orthosis per KWP 888.3050
Spinal intervertebral body fixation orthosis per KWQ 888.3050
Class II

3. Predicate or legally marketed devices which are substantially equivalent:

- APEX Spine System w/ Ti Rods (K062513 / K092825) / SpineCraft
- Beacon / Revere Ti & CoCr Rods (K092610 / K100788) / Globus
- Range / Denali Ti & CoCr Rods (K070229 / K080792) / K2M

4. **Description of the device:**

The added Ø5.50mm and Ø6.0mm CoCr Spinal Rods are identical to the existing devices of the previously cleared APEX Spine System with regards to indications for use and function. The Ø5.50mm and Ø6.0mm CoCr Rods are available in various lengths and are designed for use with the previously cleared titanium alloy components of the APEX Spine System which can accept a Ø5.50mm and/or Ø6.0mm spinal rod, including monoaxial, polyaxial screws, hooks, and connectors. The Ø5.50mm and Ø6.0mm CoCr Rods will be labelled as components of the APEX Spine System.

Materials:

CoCr28Mo6 per ASTM F1537 and ISO 5832-12
Ti-6Al-4V per ASTM F136

Function:

The APEX Spine System is indicated for 1) non-cervical spinal fixation devices intended for posterior, non-pedicle fixation, 2)for non-cervical pedicle screw fixation and 3)hook fixation systems of the non-cervical spine

5. Substantial equivalence claimed to predicate devices

APEX Spine System w/ CoCr Rods is substantially equivalent to the APEX w/ Ti Rod (K062513 / K092825), Beacon / Revere w/ Ti & CoCr Rods (K092610 / K100788) and Range / Denali w/ Ti & CoCr Rods (K070229 / K080792) in terms of intended use, design, materials used, mechanical

safety and performances,. The table below compares the features and characteristics of the APEX w/ CoCr Rods to these predicate devices.

Device Name / Items	APEX w/ CoCr Rods	APEX w/ Ti Rod	Beacon / Revere w/ Ti & CoCr Rods	Range / Denali w/ Ti & CoCr Rods
Sponsor	SpineCraft	SpineCraft	Globus	K2M
510(k) Number	Current submission	K062513 / K092825	K092610 / K100788	K070229 / K080792
Rod material	Ø5.5mm & Ø6.0mm – CoCr	Ø5.5mm & Ø6.0mm - Ti-6Al-4V alloy	Ø5.5mm & Ø6.35mm Ti-6Al-4V alloy & CoCr	Ti-6Al-4V alloy & CoCr
Screw loading	Top	Top	Top	Top
Screw material	Titanium Ti-6Al-4V alloy, per ASTM F136	Titanium Ti-6Al-4V alloy, per ASTM F136	Titanium Ti-6Al-4V alloy, per ASTM F136	Titanium Ti-6Al-4V alloy, per ASTM F136
Polyaxial screw	Has polyaxial screws	Has polyaxial screws	Has polyaxial screws	Has polyaxial screws
Monoaxial screw	Has monoaxial screws	Has monoaxial screws	Has monoaxial screws	Has monoaxial screws
Has Crosslinks?	Yes	Yes	Yes	Yes
Hooks	Laminar and Pedicle Hooks	Laminar and Pedicle Hooks	Has hooks	Has hooks
Has Washer?	Polyaxial Screw Washers	Polyaxial Screw Washers	Polyaxial Screw Washers	
Sterility	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital	Non-sterile, steam sterilized at hospital

6. **Intended Use:**

The APEX Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudo-arthrosis).

The APEX Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The APEX Spine System is also a hook and sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture

and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

7. Non-clinical Test Summary:

The following tests were conducted:

- ASTM F1717-09, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"
- ASTM F1798 (2008), "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants."

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

The APEX Spine System w/ CoCr Rods is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SpineCraft, LLC
% Ami Akallal-Asaad
Director of Regulatory Affairs
2215 Enterprise Drive
Westchester, Illinois 60154

DEC 10 2010

Re: K102488
Trade/Device Name: APEX Spine System w/CoCr Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP, KWQ
Dated: November 18, 2010
Received: November 23, 2010

Dear Ami Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indication for Use Statement

DEC 10 2010

510(k) Number (if known): K102488
Device Name: APEX Spine System

Indication for Use:

The APEX Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudo-arthrosis).

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102488